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HOUSE BILL 2686
By Campfield

AN ACT to amend Tennessee Code Annotated, Title 53, Chapter 10, relative to prescription medications.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 53, Chapter 10, is amended by adding Sections 2 through 8 of this act as a new part thereto.

SECTION 2. It is the purpose of this part to:

(1) Improve the health of needy Tennesseans through a prescription drug redispensing program that authorizes nursing home facilities and hospices to redispense medicines that would otherwise be destroyed; and

(2) Reaffirm the authority of the state board of pharmacy to protect the safety of the prescription drug supply in this state.

SECTION 3. As used in this act:

(1) "Controlled substances" means controlled substances in Schedules II, III, and IV dispensed in this state, and Schedule V controlled substances identified by the controlled substance database advisory committee created by § 53-10-303, as demonstrating a potential for abuse;

(2) "Hospice" means a facility defined as such in § 68-11-201;

(3) "Indigent" means a person with an income that is below two hundred percent (200%) of the federal poverty level;

(4) "Nursing home" means a facility defined as such in § 68-11-201;

(5)

(A)

(i) "Prescription drug" means a drug limited by § 503(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq. to being dispensed by or upon a medical practitioner's prescription because the drug is:

(a) Habit-forming;

(b) Toxic or having potential for harm; or

(c) Limited in its use to use under a practitioner's supervision by the new drug application for the drug.

(ii) The product label of a legend is required to contain the statement:

(a) "CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION"; or

(b) "Rx only".

(iii) The drug is subject to the requirement of § 503(b)(1) of the Federal Food, Drug, and Cosmetic Act which shall be exempt from § 502(f)(1) of the Federal Food, Drug, and Cosmetic Act if certain specified conditions are met.

(B) "Prescription drug", for purposes of this act, does not include controlled substances; and

(6) "Properly transferred" means the storage, handling, and distribution of a drug under this act in:

(A) Accordance with the label; and

(B) Its dispensed, sealed, tamper-evident single user unit.

SECTION 4.

(a) The prescription drug redispensing program established by this act shall be a pilot program to determine the efficacy of redispensing prescription drugs to indigent patients.

(b) The state board of pharmacy, in cooperation with the department of human services and the department of health, shall develop and implement this pilot program consistent with public health and safety through which unused prescription medications, other than controlled substances, may be transferred from a nursing home or hospice for the purpose of distributing the medication to residents of such facilities who are indigent.

(c) The state board of pharmacy, in cooperation with the department of human services and the department of health, shall monitor the pilot program and submit two (2) reports along with any recommendations or findings to the general assembly:

(1) The first report on or before January 1, 2008; and

(2) The second report on or before January 1, 2009.

(d) Participation in this pilot program by any entity, including individuals, pharmacies, nursing homes, hospices, and drug manufacturers shall be voluntary.

SECTION 5.

(a)

(1) Notwithstanding the provisions of § 53-10-104, or any other law to the contrary, a nursing home or hospice may accept for redispensing prescription drugs issued to another resident of such nursing home or hospice or from another nursing home or hospice for relabeling and dispensing free of charge and pursuant to a valid prescription order to an indigent patient.

(2) The donor patient shall be considered to be the owner of the prescription drug and entitled to donate the drug for use by residents of nursing homes and hospices.

(b)

(1)

(A)

(i) Any nursing home or hospice may enter into a contract with any nursing home or hospice for the transfer of drugs under this section.

(ii) No drugs may be transferred without a contract.

(B) A contract entered into under subdivision (b)(1)(A) of this section shall be approved by the state board of pharmacy, in cooperation with the department of human services and the department of health.

(2)

(A) A contract entered into under subdivision (b)(1)(A) of this section shall set out procedures for ensuring a safe chain of custody to protect the safety of all transferred drugs.

(B) The contract may specify that the nursing home or hospice shall:

(i) Define a specified set of drugs that will be transferred from the nursing home or hospice to other nursing homes and hospices;

(ii) Request from time to time the transfer of particular drugs;

(iii) Receive all the drugs that the nursing home is authorized to transfer under this section; or

(iv) Make such other provisions as may be approved by the state board of pharmacy.

(3) The pharmacist in charge at the nursing home or hospice shall be responsible for determining the description of the drugs that will be included in the contract.

(c) Donations of prescription drugs to a nursing home or hospice pharmacy shall meet the following requirements:

(1) The nursing home or hospice accepts such drugs only in their original sealed and tamper-evident packaging. Provided, a nursing home or hospice may accept drugs packaged in single-unit doses or blister packs with the outside packaging opened if the single-unit dose packaging remains intact;

(2) A pharmacist for such nursing home or hospice determines that the drug is not adulterated or misbranded and is safe to dispense;

(3) No product of which the integrity cannot be assured shall be accepted for redispensing by the nursing home or hospice;

(4)

(A) The donor executes a form stating that the donor is authorized to donate the drugs and intends to voluntarily donate them to a nursing home or hospice.

(B) The nursing facility retains the donor form along with other acquisition records;

(5) The donor patient's name, prescription number, and any other identifying marks are obliterated from the packaging before the nursing home or hospice sends the drug to a nursing home or hospice;

(6) The drug name, strength, and expiration date remain on the drug package label;

(7) The redispensed drug is assigned the same expiration date as on the original package;

(8) Expired drugs accepted by a nursing home or hospice are not redispensed and are destroyed according to the nursing home's or hospice's destruction procedures; and

(10) The nursing home or hospice accepts no controlled substances.

(d)

(1) If a nursing home or hospice that releases drugs to another nursing home or hospice receives notice from a pharmacy that a drug has been recalled, the nursing home or hospice shall inform the recipient nursing home or hospice of the recall.

(2) If a nursing home or hospice receives a recall notification from another nursing home or hospice, a uniform destruction of the entire recalled drug in the facility shall be conducted.

(e) No drug dispensed pursuant to this act shall be eligible for reimbursement from TennCare.

(f) Indigent patients receiving prescription drugs through this program shall sign a waiver form releasing the nursing home or hospice, the donor, and the donor's estate from liability.

(g) The board shall promulgate rules pursuant to title 4, chapter 5, to develop:

(1) Forms and procedures for authorizations and certifications required under subdivision (c)(4) of this section;

(2) The donor consent form required under subdivision (c)(4) of this section;

(3) The waiver forms required under subsection (f) of this section; and

(4) Specific requirements for nursing homes and hospices to qualify to participate in the pilot program.

(h)

(1) The following persons and entities that participate in the pilot program shall not be subject to any professional disciplinary action or criminal prosecution for actions taken under the program:

(A) The donor and the donor's estate;

(B) A nursing home;

(C) The prescribing physician, physician's assistant, registered nurse, advanced practice nurse, or nurse practitioner;

(D) Pharmacists and pharmacy technicians except where the board has promulgated regulations dealing specifically with this program;

(E) A hospice;

(F) The department of health;

(G) The department of human services; or

(H) The state board of pharmacy.

(2) Participation in the pilot program shall not be used as an independent basis for a claim of liability in tort or other civil action against any person or entity, including, but not limited to:

(A) The donor and the donor's estate;

(B) A nursing facility;

(C) The prescribing physician, physician's assistant, nurse practitioner, or nurse;

(D) A hospice;

(E) A pharmacy acting in conformity with state board of pharmacy rules and regulations;

(F) The pharmacist who originally dispensed the donated prescription drugs acting in conformity with state board of pharmacy rules and regulations;

(G) A pharmacist dispensing donated prescription drugs acting in conformity with the state board of pharmacy rules and regulations;

(H) The department of health;

(I) The department of human services; or

(J) The state board of pharmacy.

(3) In the absence of bad faith, a drug manufacturer shall not be subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a drug manufactured by the drug manufacturer that is donated by any person under the pilot program, including, but not limited to, liability for failure to provide:

(A) Product or consumer package insert information; or

(B) The expiration date of the donated drug.

(4) Subdivision (3)(A) of this section does not apply to a previously undisclosed product defect.

SECTION 6. Nothing in this act shall restrict the use of samples by a physician or advanced practical nurse during the course of working at a nursing home or hospice, whether or not the clinic has a licensed outpatient pharmacy.

SECTION 7. Nothing in this act shall be construed to provide for the resale of drugs by any person or entity.

SECTION 8. Nothing in this act applies to any issue of liability arising outside the scope of the pilot program.

SECTION 9. For the purpose of promulgating rules and regulations, this act shall take effect upon becoming a law, the public welfare requiring it. For all other purposes, this act shall take effect September 1, 2006, the public welfare requiring it. The provisions of this act shall terminate and expire July 1, 2009, the public welfare requiring it.